

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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	:	
ALCON RESEARCH, LTD.,	:	
	:	
	:	Civil Action No.: 09-CV-00318 (LDD)
Plaintiff,	:	
	:	
v.	:	JURY TRIAL DEMANDED
	:	
BARR LABORATORIES, INC.,	:	
	:	
Defendant.	:	
	:	
_____	X	

DEFENDANT BARR LABORATORIES, INC'S
ANSWER AND AFFIRMATIVE DEFENSES

Defendant Barr Laboratories, Inc. by and through the undersigned attorneys, answer the Complaint of Plaintiff Alcon Research, Ltd. ("Alcon") as follows:

ANSWER

Nature of the Action

1. Paragraph 1 is a characterization of Alcon's complaint and contains legal conclusions rather than allegations of fact to which no response is required. To the extent that a response is required, Barr admits that Alcon's complaint is for patent infringement of United States Patent No. 5,510,383 ("the '383 patent"); 5,631,287 ("the '287 patent"); 5,849,792 ("the '792 patent"); 5,889,052 ("the '052 patent") and 6,011,062 ("the '062 patent") (collectively, "the patents-in-suit"), which purport to cover the Travatan[®] product, and seeks relief under the patent laws of the United States of America, 35 United States Code, but denies that Alcon is entitled to such relief. Barr further admits that Alcon's complaint for patent infringement relates to an

Abbreviated New Drug Application (“ANDA”) Barr filed with the United States Food and Drug Administration (“FDA”) for approval to commercially market an ophthalmic solution product containing travoprost as the active ingredient. Barr denies the remaining allegations of Paragraph 1.

PARTIES

2. On information and belief, Barr admits the allegation in Paragraph 2.

3. Barr admits that it is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 400 Chestnut Ridge Road, Woodcliff Lake, NJ 07677.

JURISDICTION AND VENUE

4. Paragraph 4 of the Complaint states a legal conclusion to which no response is required. To the extent that a response is required, Barr admits that jurisdiction and venue for this action is proper in this Court. Barr denies the remaining allegations of paragraph 4.

BACKGROUND

5. Barr admits that Travatan® is an topical ophthalmic solution containing travoprost. Barr further admits that the FDA approved label specifies that Travatan® is indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension who are intolerant of other intraocular pressure lowering medications or insufficiently responsive (failed to achieve target IOP determined after multiple measurements over time) to another intraocular pressure lowering medication.

6. Barr admits that the FDA publication, *Approved Drug Products with Therapeutic Equivalence Evaluation*, lists all the patents-in-suit in this matter in connection with

TRAVATAN®. To the extent that Paragraph 6 of the Complaint contains any additional allegations, Barr denies them.

7. Barr admits that it sent a Notification Letter to Alcon on or about March 17, 2009 to give notice that Barr had filed with the FDA ANDA No. 91-109, including its Paragraph IV Certifications, for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of travoprost ophthalmic solution 0.004% prior to the expiration of the patents-in-suit. To the extent that Paragraph 7 of the Complaint contains any additional allegations, Barr denies them.

8. Barr admits that its ANDA No. 91-109 contained Paragraph IV Certifications pursuant to Section 505(j)(2)(A)(vii)(IV) of the FDCA and 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the patents-in-suit are invalid, unenforceable and/or not be infringed by the manufacture, use, offer for sale, sale, or importation of Barr's ANDA Product. To the extent that Paragraph 8 of the Complaint contains any additional allegations, Barr denies them.

COUNT 1 - U.S. PATENT NO. 5,510,383

9. Barr hereby incorporates by reference its answers from Paragraphs 1 to 8 as if fully set forth herein.

10. Barr admits that the Patent and Trademark Office ("PTO") states that the '383 patent was issued on April 23, 1996, but specifically denies that the patent was duly or legally issued. Barr further admits that the PTO lists John E. Bishop, Louis DeSantis, Jr., and Verney L. Sallee as the inventors of the '383 patent entitled "Use of Cloprostenol, Fluprostenol and Their Salts and Esters to Treat Glaucoma and Ocular Hypertension" and that the PTO lists

Alcon Laboratories, Inc. as the assignee of the '383 patent. Barr admits that a copy of the '383 patent was attached to the Complaint as Exhibit A. Barr denies the remainder of Paragraph 10.

11. Barr admits that the electronic assignment records of the PTO identifies Alcon Laboratories, Inc. as the assignee of the '383 patent. However, Barr lacks sufficient knowledge or information sufficient to form a belief as to the truth of the allegation that the '383 patent was subsequently assigned to Alcon Research, Ltd., and therefore denies the same.

12. Barr denies the allegations in Paragraph 12.

13. Barr admits that it is aware of the existence of the '383 patent. Barr denies each and every remaining allegation in Paragraph 13.

14. Barr admits that it has submitted ANDA 91-109 including Paragraph IV certifications, to obtain FDA approval for the commercial manufacture, use, offer to sell, sale, and/or importation of Barr's ANDA Product into the United States before the expiration of the '383 patent which can constitute a technical act of infringement under 35 U.S.C. § 271(e)(2)(A). However, Barr specifically denies that ANDA No. 91-109 infringes any valid claim of the '383 patent and Barr denies the remaining allegations of Paragraph 14.

15. Barr denies that the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Barr's ANDA Product infringes any valid claim of the '383 patent. Barr denies each and every remaining allegation in Paragraph 15.

16. Barr admits that it has submitted ANDA No. 91-109 to engage in the manufacture, use, offer to sell, sale, and/or importation of Barr's ANDA Product. Barr denies the remaining allegations of Paragraph 16.

17. Barr denies that the use of Barr's ANDA Product in accordance with and directed by Barr's proposed labeling infringes any valid claim of the '383 patent. Barr denies each and every remaining allegation in Paragraph 17.

18. Barr denies the allegations in Paragraph 18.

19. Barr denies the allegations in Paragraph 19.

20. Barr denies the allegations in Paragraph 20.

21. Barr denies the allegations in Paragraph 21.

22. Barr denies the allegations in Paragraph 22.

COUNT II: U.S. PATENT NO. 5,631,287

23. Barr hereby incorporates by reference its answers from Paragraphs 1 to 22 as if fully set forth herein.

24. Barr admits that the PTO states that the '287 patent was issued on May 20, 1997, but specifically denies that the patent was duly or legally issued. Barr further admits that the PTO lists L. Wayne Schneider as the inventor of the '287 patent entitled "Storage-Stable Prostaglandin Compositions" and that the PTO lists Alcon Laboratories, Inc. as the assignee of the '287 patent. Barr admits that a copy of the '287 patent was attached to the Complaint as Exhibit B. Barr denies the remainder of Paragraph 24.

25. Barr admits that the electronic assignment records of the PTO identifies Alcon Laboratories, Inc. as the assignee of the '287 patent. However, Barr lacks sufficient knowledge or information sufficient to form a belief as to the truth of the allegation that the '287 patent was subsequently assigned to Alcon Research, Ltd., and therefore denies the same.

26. Barr denies the allegations in Paragraph 26.

27. Barr admits that it is aware of the existence of the '287 patent. Barr denies each and every remaining allegation in Paragraph 27.

28. Barr admits that it has submitted ANDA 91-109 including Paragraph IV certifications, to obtain FDA approval for the commercial manufacture, use, offer to sell, sale, and/or importation of Barr's ANDA Product into the United States before the expiration of the '297 patent which can constitute a technical act of infringement under 35 U.S.C. § 271(e)(2)(A). However, Barr specifically denies that ANDA No. 91-109 infringes any valid claim of the '287 patent and Barr denies the remaining allegations of Paragraph 28.

29. Barr denies that the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Barr's ANDA Product infringes any valid claim of the '287 patent. Barr denies each and every remaining allegation in Paragraph 29.

30. Barr admits that it has submitted ANDA No. 91-109 to engage in the manufacture, use, offer to sell, sale, and/or importation of Barr's ANDA Product. Barr denies the remaining allegations of Paragraph 30.

31. Barr denies the allegations in Paragraph 31.

32. Barr denies the allegations in Paragraph 32.

33. Barr denies the allegations in Paragraph 33.

34. Barr denies the allegations in Paragraph 34.

35. Barr denies the allegations in Paragraph 35.

COUNT III: U.S. PATENT NO. 5,849,792

36. Barr hereby incorporates by reference its answers from Paragraphs 1 to 35 as if fully set forth herein.

37. Barr admits that the PTO states that the '792 patent was issued on Dec. 15, 1998, but specifically denies that the patent was duly or legally issued. Barr further admits that the PTO lists L. Wayne Schneider as the inventor of the '792 patent entitled "Storage-Stable Prostaglandin Compositions" and that the PTO lists Alcon Laboratories, Inc. as the assignee of the '792 patent. Barr admits that a copy of the '792 patent was attached to the Complaint as Exhibit C. Barr denies the remainder of Paragraph 37.

38. Barr admits that the electronic assignment records of the PTO identifies Alcon Laboratories, Inc. as the assignee of the '792 patent. However, Barr lacks sufficient knowledge or information sufficient to form a belief as to the truth of the allegation that the '792 patent was subsequently assigned to Alcon Research, Ltd., and therefore denies the same.

39. Barr denies the allegations in Paragraph 39.

40. Barr admits that it is aware of the existence of the '792 patent. Barr denies each and every remaining allegation in Paragraph 40.

41. Barr admits that it has submitted ANDA 91-109 including Paragraph IV certifications, to obtain FDA approval for the commercial manufacture, use, offer to sell, sale, and/or importation of Barr's ANDA Product into the United States before the expiration of the '792 patent which can constitute a technical act of infringement under 35 U.S.C. § 271(e)(2)(A). However, Barr specifically denies that ANDA No. 91-109 infringes any valid claim of the '792 patent and Barr denies the remaining allegations of Paragraph 41.

42. Barr denies that the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Barr's ANDA Product infringes any valid claim of the '792 patent. Barr denies each and every remaining allegation in Paragraph 42.

43. Barr admits that it has submitted ANDA No. 91-109 to engage in the manufacture, use, offer to sell, sale, and/or importation of Barr's ANDA Product. Barr denies the remaining allegations of Paragraph 43.

44. Barr denies that the use of Barr's ANDA Product in accordance with and directed by Barr's proposed labeling infringes any valid claim of the '792 patent. Barr denies each and every remaining allegation in Paragraph 44.

45. Barr denies the allegations in Paragraph 45.

46. Barr denies the allegations in Paragraph 46.

47. Barr denies the allegations in Paragraph 47.

48. Barr denies the allegations in Paragraph 48.

49. Barr denies the allegations in Paragraph 49.

COUNT IV: U.S. PATENT NO. 5,889,052

50. Barr hereby incorporates by reference its answers from Paragraphs 1 to 49 as if fully set forth herein.

51. Barr admits that the PTO states that the '052 patent was issued on March 30, 1999, but specifically denies that the patent was duly or legally issued. Barr further admits that the PTO lists Peter G. Klimko, John E. Bishop, Verney L. Sallee, and Paul W. Zinke as the inventors of the '052 patent entitled "Use of Cloprostenol and Fluprostenol Analogues to Treat Glaucoma and Ocular Hypertension" and that the PTO lists Alcon Laboratories, Inc. as the assignee of the '052 patent. Barr admits that a copy of the '052 patent was attached to the Complaint as Exhibit D. Barr denies the remainder of Paragraph 51.

52. Barr admits that the electronic assignment records of the PTO identifies Alcon Laboratories, Inc. as the assignee of the '052 patent. However, Barr lacks sufficient

knowledge or information sufficient to form a belief as to the truth of the allegation that the '052 patent was subsequently assigned to Alcon Research, Ltd., and therefore denies the same.

53. Barr denies the allegations in Paragraph 53.

54. Barr admits that it is aware of the existence of the '052 patent. Barr denies each and every remaining allegation in Paragraph 54.

55. Barr admits that it has submitted ANDA 91-109 including Paragraph IV certifications, to obtain FDA approval for the commercial manufacture, use, offer to sell, sale, and/or importation of Barr's ANDA Product into the United States before the expiration of the '052 patent which can constitute a technical act of infringement under 35 U.S.C. § 271(e)(2)(A). However, Barr specifically denies that ANDA No. 91-109 infringes any valid claim of the '052 patent and Barr denies the remaining allegations of Paragraph 55.

56. Barr denies that the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Barr's ANDA Product infringes any valid claim of the '052 patent. Barr denies each and every remaining allegation in Paragraph 56.

57. Barr admits that it has submitted ANDA No. 91-109 to engage in the manufacture, use, offer to sell, sale, and/or importation of Barr's ANDA Product. Barr denies the remaining allegations of Paragraph 57.

58. Barr denies that the use of Barr's ANDA Product in accordance with and directed by Barr's proposed labeling infringes any valid claim of the '052 patent. Barr denies each and every remaining allegation in Paragraph 58.

59. Barr denies the allegations in Paragraph 59.

60. Barr denies the allegations in Paragraph 60.

61. Barr denies the allegations in Paragraph 61.

62. Barr denies the allegations in Paragraph 62.

63. Barr denies the allegations in Paragraph 63.

COUNT V: U.S. PATENT NO. 6,011,062

64. Barr hereby incorporates by reference its answers from Paragraphs 1 to 63 as if fully set forth herein.

65. Barr admits that the PTO states that the '062 patent was issued on Jan. 4, 2000, but specifically denies that the patent was duly or legally issued. Barr further admits that the PTO lists L. Wayne Schneider, Rajan Bawa, and Alan L. Weiner as the inventors of the '062 patent entitled "Storage-Stable Prostaglandin Compositions" and that the PTO lists Alcon Laboratories, Inc. as the assignee of the '062 patent. Barr admits that a copy of the '062 patent was attached to the Complaint as Exhibit E. Barr denies the remainder of Paragraph 65.

66. Barr admits that the electronic assignment records of the PTO identifies Alcon Laboratories, Inc. as the assignee of the '062 patent. However, Barr lacks sufficient knowledge or information sufficient to form a belief as to the truth of the allegation that the '062 patent was subsequently assigned to Alcon Research, Ltd., and therefore denies the same.

67. Barr denies the allegations in Paragraph 67.

68. Barr admits that it is aware of the existence of the '062 patent. Barr denies each and every remaining allegation in Paragraph 68.

69. Barr admits that it has submitted ANDA 91-109 including Paragraph IV certifications, to obtain FDA approval for the commercial manufacture, use, offer to sell, sale, and/or importation of Barr's ANDA Product into the United States before the expiration of the '062 patent which can constitute a technical act of infringement under 35 U.S.C. § 271(e)(2)(A).

However, Barr specifically denies that ANDA No. 91-109 infringes any valid claim of the '062 patent and Barr denies the remaining allegations of Paragraph 69.

70. Barr denies that the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Barr's ANDA Product infringes any valid claim of the '062 patent. Barr denies each and every remaining allegation in Paragraph 70.

71. Barr admits that it has submitted ANDA No. 91-109 to engage in the manufacture, use, offer to sell, sale, and/or importation of Barr's ANDA Product. Barr denies the remaining allegations of Paragraph 71.

72. Barr denies that the use of Barr's ANDA Product in accordance with and directed by Barr's proposed labeling infringes any valid claim of the '062 patent. Barr denies each and every remaining allegation in Paragraph 72.

73. Barr denies the allegations in Paragraph 73

74. Barr denies the allegations in Paragraph 74.

75. Barr denies the allegations in Paragraph 75.

76. Barr denies the allegations in Paragraph 76.

Prayer For Relief

Barr denies that Alcon is entitled to any relief from the Court.

AFFIRMATIVE DEFENSES

Barr sets forth the following affirmative and other defenses. Barr does not intend hereby to assume the burden of proof with respect to those matters as to which, pursuant to law, Alcon bears the burden.

First Affirmative Defense

(Invalidity of '383 Patent)

1. One or more claims of the '383 patent are invalid for failure to satisfy the provisions of one or more of sections 101, 102, 103, and/or 112 of Title 35 of the United States Code.

Second Affirmative Defense

(Invalidity of '287 Patent)

2. One or more claims of the '287 patent are invalid for failure to satisfy the provisions of one or more of sections 101, 102, 103, and/or 112 of Title 35 of the United States Code.

Third Affirmative Defense

(Invalidity of '792 Patent)

3. One or more claims of the '792 patent are invalid for failure to satisfy the provisions of one or more of sections 101, 102, 103, and/or 112 of Title 35 of the United States Code.

Fourth Affirmative Defense

(Invalidity of '052 Patent)

4. One or more claims of the '052 patent are invalid for failure to satisfy the provisions of one or more of sections 101, 102, 103, and/or 112 of Title 35 of the United States Code.

Fifth Affirmative Defense

(Invalidity of '062 Patent)

5. One or more claims of the '062 patent are invalid for failure to satisfy the provisions of one or more of sections 101, 102, 103, and/or 112 of Title 35 of the United States Code.

Sixth Affirmative Defense

(Noninfringement of '383 Patent)

6. The manufacture, use, sale, or offer for sale of Barr's travoprost ophthalmic solution 0.004% ANDA product has not infringed, does not infringe, and would not, if marketed, infringe any valid and enforceable claims of the '383 patent.

Seventh Affirmative Defense

(Noninfringement of '287 Patent)

7. The manufacture, use, sale, or offer for sale of Barr's travoprost ophthalmic solution 0.004% ANDA product has not infringed, does not infringe, and would not, if marketed, infringe any valid and enforceable claims of the '287 patent.

Eighth Affirmative Defense

(Noninfringement of '792 Patent)

8. The manufacture, use, sale, or offer for sale of Barr's travoprost ophthalmic solution 0.004% ANDA product has not infringed, does not infringe, and would not, if marketed, infringe any valid and enforceable claims of the '792 patent.

Ninth Affirmative Defense

(Noninfringement of '052 Patent)

9. The manufacture, use, sale, or offer for sale of Barr's travoprost ophthalmic solution 0.004% ANDA product has not infringed, does not infringe, and would not, if marketed, infringe any valid and enforceable claims of the '052 patent.

Tenth Affirmative Defense

(Noninfringement of '062 Patent)

10. The manufacture, use, sale, or offer for sale of Barr's travoprost ophthalmic solution 0.004% ANDA product has not infringed, does not infringe, and would not, if marketed, infringe any valid and enforceable claims of the '062 patent.

Eleventh Affirmative Defense

(Failure to State a Claim)

11. Alcon's Complaint, in whole or in part, fails to state a claim upon which relief can be granted.

Twelfth Affirmative Defense

12. Any additional defenses that discovery may reveal.

PRAYER FOR RELIEF

WHEREFORE, Defendant Plaintiff Barr Laboratories, Inc. prays that the Court enter judgment against Plaintiff Alcon Research, Ltd., and in favor of Defendant Barr Laboratories, Inc. as follows:

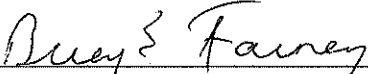
- A. Dismiss the Complaint with prejudice and deny each request for relief made by Plaintiff;
- B. For a declaration that Barr Laboratories, Inc.'s ANDA product does not and will not infringe claims of U.S. Patent No. 5,510,383;
- C. For a declaration that the claims of U.S. Patent No. 5,510,383 are invalid;
- D. For a declaration that Barr Laboratories, Inc.'s ANDA product does not and will not infringe the claims of U.S. Patent No. 5,631,287;
- E. For a declaration that the claims of U.S. Patent No. 5,631,287 are invalid;
- F. For a declaration that Barr Laboratories, Inc.'s ANDA product does not and will not infringe the claims of U.S. Patent No. 5,849,792;

- G. For a declaration that the claims of U.S. Patent No. 5,849,792 are invalid;
- H. For a declaration that Barr Laboratories, Inc.'s ANDA product does not and will not infringe the claims of U.S. Patent No. 5,889,052;
- I. For a declaration that the claims of U.S. Patent No. 5,889,052 are invalid;
- J. For a declaration that Barr Laboratories, Inc.'s ANDA product does not and will not infringe the claims of U.S. Patent No. 6,011,062;
- K. For a declaration that the claims of U.S. Patent No. 6,011,062 are invalid;
- L. For an award of attorneys' fees pursuant to 35 U.S.C. § 285, other statutes or rules, or the general power of the Court;
- M. For an award of costs;
- N. Preliminarily and permanently enjoin Plaintiff, their officers, agents, servants, employees, attorneys, and any person who acts in concert or participation with Plaintiffs, from utilizing the patents-in-suit to block, hamper, hinder or obstruct FDA approval of Barr's Proposed Product;
- O. Permanently enjoin Plaintiff, their officers, agents, servants, employees, attorneys, and any person who acts in concert or participation with Plaintiff, from asserting or otherwise seeking to enforce the patents-in-suit against Barr or anyone in privity with Barr; and
- P. For such other relief as the Court determines to be just and proper.

JURY DEMAND

Defendant Barr Laboratories, Inc. requests a jury trial on all issues so triable.

Respectfully submitted,



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